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(54) Title: INTRAOSSEOUS SOFT TISSUE-TO-BONE ANCHOR AND METHOD OF USING THE DEVICES

(57) Abstract: This is a surgical device. More particularly, it is an intraosseous anchor for securing soft tissue, such as a tendon or ligament, to a cavity formed in a bone. The device itself preferably is formed in such a way that the soft tissue is pressed against the bone by the device to accelerate growth by the soft tissue and attachment to the bone. The device preferably utilizes anchor barbas on its exterior to grasp the soft tissue under conditions of improved distribution of tension and with a minimal disruption of the soft tissue-bone interface and the allied nutrient supplies. the anchor and soft tissue may be treated with osteogenic growth factors. Various processes of using the device are also shown.

INTRAOSSEOUS SOFT TISSUE-TO-BONE ANCHOR AND METHOD OF USING THE DEVICES

FIELD OF THE INVENTION

This invention is in the field of surgery. More particularly, it relates to an intraosseous anchor for securing soft tissue, such as a tendon or ligament, to a cavity formed in a bone. The device itself preferably is formed in such a way that the soft tissue is pressed against the bone by the device to accelerate growth by the soft tissue and attachment to the bone. The device preferably utilizes anchor barbs on its exterior to grasp the soft tissue under conditions of improved distribution of tension and with a minimal disruption of the soft tissue-bone interface and the allied nutrient supplies. The invention also includes combinations of the device with the soft tissue graft and various growth factors. Processes of using the inventive device are also a portion of the invention.

DESCRIPTION OF RELATED ART

There are a variety of orthopedic surgery procedures which sometimes require the attachment or reattachment of soft tissue flexible members to a bone. One such common procedure is the replacement of an anterior cruciate ligament graft in the knee. The ends of such grafts are typically attached within bone tunnels drilled into the respective bones. The attachment is then completed by use of a compression or interference-fit screws or the like.

Typical of such devices used to press one end of a flexible member against the interior wall of a bone cavity include U.S. Patent Number 6,123,711, to Winters, U.S. Patent 5,454,811, to Hubner; U.S. Patent 5,425,767, to Steininger et al.; and U.S. Patent 5,062,843, to Mahony.

No cited references show the devices nor the procedures described herein.

SUMMARY OF THE INVENTION

As noted below, this invention relates to an intra-osseous soft tissue-to-bone anchor for contacting soft tissue with an opening in a bone. The device is made up of a longitudinal fixture having a distal and a proximal end and an exterior surface. The proximal end preferably has an opening (generally integral with the exterior surface cavity discussed just below) for passage of the soft tissue graft proximally of the device. The distal end preferably is configured for entry into that bone opening. The exterior surface preferably has at least one external cavity containing anchor barbs to graspingly accept the soft tissue and they are sized and oriented to press the soft tissue within the bone opening against the bone wall. The exterior surface is also adapted for anchoring the anchor in the opening.

The exterior surface cavity preferably is longitudinal along the body of the device. There may be more than one cavity. Desirably, at least one diametric passageway extends between or among the various multiple exterior cavities for passage of soft tissue.

The distal end generally is adapted for entering the bone opening by, e.g., chamfering the end or providing a distal end opening.

The exterior surface may be adapted for anchoring in the bone opening via placement of, e.g., one or more circumferential ridges or knob-like protuberances on the exterior surface or by use of movable protuberances perhaps which are movable and rotate into the exterior surface from the interior.

The exterior surface itself is generally cylindrical (allowing, of course for the exterior cavities). The surface may be threaded or have a cut from one end to the other allowing a snap fit into a generally cylindrical shape from a generally spiral shape. The interior surface may include soft tissue barbs. The anchor may be of a shape which is notched to provide a "splay" at the proximal end and provide tension against the bone

interior wall. The device may be formed in two parts: a saddle part making up a portion of the exterior surface and having an inner surface and a rail part which slides into the saddle part and forms the external cavities.

The exterior surface may be a folded "V" having a distal fold, an exterior wall, and an opening through said exterior wall near the fold or it may also be a generally rectangular sheet having at least one passageway between the proximal end and the distal end for passage of soft tissue between the proximal and distal end, perhaps having exterior protuberances and soft tissue barbs in the passageway.

Additionally, the anchor structure may have extendable spring wings or arms which extend into the softer bone areas beneath the cortical plate. The proximal end may be made up of multiple longitudinal spring arms splayed at (or making up) the proximal end.

The inventive anchor is preferably made of at least on biodegradable polymer or copolymer, such as polyglycolide, polylactide, poly-α-caprolactone, polydiaxanone, polyglyconate, polylactide-co-glycolide, their mixtures, alloys, and random and block copolymers.

The various devices may further be a combination of the soft tissue graft and an osteogenic growth factor.

Another variation of the inventive device is a spiral intra-osseous soft tissue-to-bone anchor made up of a spirally wound sheet having a longitudinal axis, an interior surface for graspingly accepting a soft tissue, e.g., a tendon and ligament, along that axis when the spirally wound sheet is collapsed around the soft tissue. The exterior surface is adapted, by integral or formed grooving or by radial protruberances to anchor to the bone opening. The spirally wound sheet may be foraminous or not. The interior surface may be grooved or have anchor barbs to grasp and hold the soft tissue graft in the anchor.

The materials of construction for this variation are the same as those mentioned above. Similarly this variation may include the soft tissue graft and an osteogenic growth factor.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A, 1B, 1C show respectively perspective and cross-sectional views of one variation of the inventive anchor device having external cavities for pressing soft tissue against the surface of a bone cavity.

Figure 2A shows another variation of the inventive device which uses a spring pressure to maintain placement of the device within the bone cavity.

Figure 2B shows steps of installing the device of Figure 2A in a bone cavity.

Figure 3 shows another variation of the inventive anchor device.

Figures 4A and 4B show respectively a side view and end views of the variations of the inventive anchor device in which the barbs mechanically expand from the interior of the device into the bone.

Figure 4C shows manner in which the device may be molded in a single piece and assembled.

Figure 4D shows the introduction of drive pin into the device of Figures 4A, 4B, and 4C to mechanically expand the barbs.

Figures 5A, 5B, and 5C show, respectively, perspective and end views of the device made according to the invention.

Figure 6A shows a perspective view of a two-piece variation of the inventive anchor device.

Figure 6B shows an in view of the assembled Figure 6A device.

Figures 7A and 7B show, respectively, side and end views of a variation of the device having exterior soft tissue cavities and exterior spring catches for anchoring the device within the bone.

Figures 8A and 8B show, respectively, side and end views of a bone anchor made according to the invention having no interior cavities.

Figures 9A and 9B show, respectively, side and end views of a screw-like device having exterior soft tissue cavities.

Figures 10A and 10B show, respectively, side and end views of a snap-fit spiral realm device for pressing soft tissue into bone cavity.

Figures 11A and 11B show, respectively, side and end views of a snap-fit device in which both the interior and exterior of the device are equipped with barbs to hold soft tissue in place.

Figures 12A and 12B show, respectively, cross-sectional and end views of a conical device having soft tissue barbs on the interior.

Figures 13A, 13B, 13C, and 13D show respectively a top view, side view, end view, and a view as-installed in a slot-shaped cavity in a bone.

Figures 14A and 14B show respectively top views and side views of a device made according to the invention having exterior and interior cavities equipped with soft tissue barbs for retaining soft tissue in the device. This variation is also installed in a slot-shaped cavity in a bone.

Figures 15A and 15B show respectively a perspective view and as-installed, cross-sectional view of a device made according to the invention. This variation is a foraminous device which utilizes a groove on the interior to grasp the soft tissue and a groove on the exterior to secure the assembly to the bone.

Figure 16 shows a variation of the device shown in Figures 15A and 15B having interior tissue-grasping tines and exterior protuberances for securing the device to the bone.

Figure 17 shows a variation of the device depicted in Figures 15A and 15B which is not foraminous.

Figure 18 shows a variation of the device shown in Figure 15A having alternative for grasping the bone and the soft tissue.

Figures 19A, 19B, and 19C show, respectively, a perspective view, a cross-sectional view, and as-installed view of device which grasps soft tissue using an interior spring-like member.

Figures 20A, 20B, and 20C show, respectively, a perspective view, side view (during installation), and a side view (after installation) of variation of the invention device which snap-fits into a bone cavity.

Figures 21A, 21B, and 21C show, respectively, side view of variation of the inventive device during installation, after installation, and a side, cross-sectional view after installation.

DESCRIPTION OF THE INVENTION

As noted elsewhere, this invention is an intraosseous anchor for securely attaching soft tissue such as a tendon or ligament to a cavity specifically produced by surgeon for holding the inventive device. Preferably, although not necessarily as will be shown below, the device is fashioned in such a way that it holds the soft tissue against the interior surface of the bone cavity. Further, it is highly desirable that the inventive device and the soft tissue be installed in a single step. Generally, or at least preferably, the devices will entail external or internal cavities which are situated in such a way that the device will grasp the soft tissue using some type of soft tissue attachment points. Generally, we will refer to those attachment points as "tines" or "prongs". These tines will refer both to points which are either sharp, i.e., able to separate tissue at chosen use, or blunt, i.e., not able to separate tissue in that use. The attachment points may also be referred to as "barbs" when those points have retaining point positioned in several of the figures discussed below.

The shape of the soft tissue points or barbs may be varied depending upon the size and type of tissue requiring grasping. Various tines or barbs may canted or erect. Various shapes include those approximating thorns, arrowheads, hooks, nails, sharpened pencils, or the like. The attachment points may be canted in a selected direction or may be radial in direction. They may be barbed, double barbed, or the like, all as desired. Further information relating to these barbs or tines may be found in U.S. Patent Application Serial No. 09/574,603 May 19, 2000, (attorney docket No. 23569-20001.00), the entirety of which is incorporated by reference.

We prefer to use biodegradable polymers as materials of construction in our devices. Polymers synthesized from monomers comprising esters, anhydrides, ortho esters, and amides are suitable for use as biodegradable materials. Specific examples of a biodegradable polymers are polyglycolide, polylactide, poly-α-caprolactone, polydioxanone, polyglyconate, copolymers of polylactide and polyglycolide, and the block and random copolymers of these polymers. Copolymers of glycolic, lactic, and other α-hydroxy acids are highly desirable. Although we prefer to use a single polymer or copolymer in a specific device, generally for ease of construction by molding, the invention is not so limited. Of course, an example of the inventive device may be made of two or more types of polymers or copolymers, or of differing molecular weights of the same polymer or copolymer. For instance, the backing material might be produced from a more flexible polymer and the points or tines from a stiffer material. These polymers have been safely used in suture materials, stents, drug delivery devices, orthopedic fixation devices, and intestinal anastomotic rings.

By "soft tissue" herein is normally meant tendons or ligaments. This is so simply because the body readily grows natural connections between these types of soft tissue and bone. In some instances, muscle fibers may be included.

In any event, the soft tissue may be autologous material, allograft material, xenograft, and organic or inorganic material, and mixtures or engineering constructs of the materials. For instance, suitable ligament xenografts are described in U.S. Patent No. 6,110,206, to Stone, and tissue-engineered tendons and ligaments are shown in U.S. Patent No. 6,023,727, to Vacanti et al. Harvested or donor soft tissue is an obvious choice for the soft tissue described herein.

As noted above, each of the devices described herein as of the type is installed as a combination of the inventive device and the soft tissue graft. This invention includes combinations of the soft tissue graft and the inventive anchor.

Finally, the invention includes independent combinations of the inventive anchor, soft tissue, and certain growth factors. Bone healing is an intricate biologic process in which the bone's structural integrity is restored through the regeneration of bone. Recent orthopedic literature has focused on proteins that enhance bone formation, thus increasing the "osteoinductive" potential. Specific proteins called growth factors have been shown to play a role in osteoinduction. These include bone morphogenetic protein (BMP), transforming growth factor beta (TGFB), platelet derived growth factor (PDGF), fibroblast growth factor (FGF) and insulin-like growth factor (ILGF). Of these, BMP has proven to be the most potent osteoinductive agent in laboratory animals by Cook (CORR 310: 1994), Gerhart (CORR 293: 1993), and Yasko (JBJS 74: 1992). Indeed, studies are now beginning on human subjects (Boden, AAOS abstract, Anaheim 1999).

BMP's are growth factors that can be made in large quantities with current recombinant gene technology. Absorbable polymers have been shown to be good carriers for BMP and promote new bone formation in vitro (Boyan, J Biomed Mater Res, July 1999).

The noted growth factors may be introduced variously onto the surface of the anchors, into the interior of the inventive anchors, or to the soft tissue graft, particularly the soft tissue graft portion that is introduced into the cavity formed within the bone.

EXTERNALLY PLACED CAVITY SOFT TISSUE-TO-BONE ANCHORS

Figures 1A shows the first variation of inventive anchor (100). Anchor (100) has a distal end (102), a proximal end (104), and an exterior surface which has at least one cavity (106) with soft tissue barbs (108). As may be seen from Figure 1C, the exterior cavity (106) may be repeated, e.g., (110), on other parts of the device (100). The exterior cavities (106), (110) are sized in such a way that the barbs (108) press into the soft tissue and in turn, the back walls of the cavities (106), (110) press the soft tissue against the bony wall into which device (100) is placed. It is common in these types of orthopedic procedures to drill a hole of a specific size into the bone suitable for accepting the device. The device is introduced via simple pressure or by impact. Also found in Figure 1A is a transverse passageway (112) which passes (as shown in Figure 1B) from exterior cavity (106) to exterior cavity (110). The soft tissue, as should be apparent, is usually long and passes along one of the exterior cavities (106), (110) through passageway (112) and returns towards proximal end (104) via the remaining exterior cavity (106), (110). The shaft of the longitudinal fixture forming the anchor (100) may also have a variety of protuberances (114) placed along the shaft.

The distal end (102) of device (100) is adapted for entering the cavity formed in the bone. Such adaptation may include chamfering, e.g., via the chamfer (116) as shown in Figure 1A and, perhaps with the distal passageway (118) also shown in Figure 1A. Distal passageway (118) may be generally for pressure release of fluids during introduction of the device (100) into the chosen or crafted bone cavity. It also allows nutrient passage to the soft tissue during its traverse through passageway (112).

Figure 2A shows another variation of the inventive device (130). This variation of the invention relies, in addition to the exterior protuberances or barbs (132) upon an included spring action between the halves (134), (136) of the device. The slot (138) between halves (134), (136) allows such a spring action as is shown in Figure 2B. In any event, the proximal end (140) of the device includes an opening (142) which is a portion of the exterior cavity (144). Second cavity (146) is also found in the variation (130) shown in Figure 2A.

Figure 2B shows the steps of introducing the device shown in Figure 2A into a cavity (148) in bone (150).

As shown in step 1 of Figure 2B, the inventive device (130) has a certain amount of "splay". This splay provides (depending on the composition of the material, of course) some definite amount of overall springiness which is used to secure the device (130) in the hole (148) when as shown in step 2. The pathway of soft tissue (152) through the device is also shown in step one of Figure 2B. The soft tissues wends its way through passageway (154), through slot (138), through passageway (156), along the partial longitudinal cavity (146), and back through passageway (158) into slot (138). In this way, the soft tissue is held both in the external cavity (142) through which it protrudes out of the bone through opening (144) and along passageway (146). It is within the scope of the invention that soft tissue barbs be found in each of exterior cavities (144) and (146). Further, the shorter exterior cavity (146) may be extended to the proximal end of the device (130) if so desired.

Figure 3 shows another variation of the inventive anchor (160), again utilizing a slot (162) which provides springiness between the halves (164), (166) of device (160). In this instance, the external protuberance is (168) are ridges which are generally circumferential around non-cavity portions of the exterior surface of the device (160). This variation (160) similarly has soft tissue barbs (170) and a cross passageway (172). The opposite face of the device (160) shown in Figure 3 may or may not have an exterior cavity as is shown in the view of Figure 3. The distal portion of the device is also adapted, perhaps by a chamfer (176) and a distal passageway (178) to allow introduction of the device (160) into a chosen bone opening. It should be apparent that the opening (178) is placed there to prevent "pressure lock" during installation and passage of nutrients to the soft tissue in passageway (172), but it should be noted normally it would pass all the way into and intersect into passageway (172). It need not, however, do so.

Figure 4A shows a variation (180) of the device in which the radial protuberance is (182) mechanically deployed using a pin (184) (as shown in Figure 4D) after the device (180) and its attendant soft tissue are placed in the crafted hole in the boneface. As is the case with the variations discussed above, this variation (180) may include a cross passageway (184), one or more exterior cavities (186) with soft tissue barbs (188). The distal end (190) may also include a chamfer (192) and a longitudinal, distal passageway (194). The moveable bone barbs or protuberances (182) are considered a portion of the external surface of this device.

Figure 4B shows an end view of a device (180) displaying the moveable radial protuberances (182) and, in this case, two external cavities (186). As noted above, although two external cavities (186) are shown here, the number of external cavities may only be a single one or may be a multiplicity, e.g., two, three, four or more. The seam (188) allowing the device to be molded in a single piece is seen.

Figure 4C shows device (180) in an "as molded" condition. By careful design, this device may be molded in a single piece. The rotating barbs (182) are hinged so that

as they rotate towards the exterior device upon the impetus of pin (184) as shown in Figure 4D, they dig into the interior of the crafted bone hole and secure device (180) in place.

Figure 5A shows another variation of the inventive device (190) having four spring arms, two spring arms (192), (194) having exterior cavities (196) for soft tissue passage. Similarly, the other two spring arms (198) and (200) include protuberances (202) for engagement with the interior of the bone hole. Again, the exterior cavities (196) include soft tissue barbs (204).

Figure 5B shows the splay of the various spring arms (198), (200) (with protuberances (202)) and spring arms (192), (194) with external cavities (196).

Figure 5C shows device (190) after installation in a bone hole (without soft tissue or, indeed, the bone) to show how the various spring arms are pulled together when installed in a hole in the bone.

Figure 6A shows a two part device (210) made up of a saddle section (212) and a rail portion (214). As a side note, although each of these devices allows relatively easy adjustment of the length of the soft tissue to be used with the inventive anchor, this variation may be the easiest to use. The saddle portion (212) may include the external protuberances (216) as are described elsewhere and a distal end (218) having a chamfer 220 and an optional distal passageway (222) (not seen in Figure 6A). In any event, the saddle portion (212) includes slots (224) to allow engaging keys (226) to slide down to engagement notches (228) to secure locking between rail portion (214) and saddle portion (212).

In this variation, the as assembled includes one or more cavities (228) having at least one proximal opening to allow passage of the included soft tissue proximally of the device. Again, the external cavities (228) preferably having soft tissue barbs (230) included therein.

Figure 6B shows an end view of the assembled device having rail portion (214) within saddle section (212). The external protuberances (216) for holding the device (210) within the bone cavity is also shown. The slot (218) as shown in Figure 6A is also seen in Figure 6B.

Figure 7A shows a side view of a variation of the device (250) having two separate methods of providing springing to the device (250). Particularly, the device has extensions (252) which are preferably made of spring metal such as a biocompatible stainless steel, or preferably nickel-titanium, material, such as nitinol. These wings (252) preferably are spaced in such a way that when they extend after installation, they are in the "marrow" portion of the bone below the cortical plate. Indeed it is preferred that wings (252) expand and are held against the lower side of the cortical plate. Additionally, the proximal end (254) of the device (250) may be splayed about the slot (256) in the manner shown in several of the variations described above. This allows a secure fixation of device (250) within a hole in a bone. This variation shown in Figure 7A and as shown in Figure 7B similarly has one exterior cavity (258) preferably with soft tissue barbs (260) as has been noted above.

Variation (250) includes as a portion of its at least one exterior cavity (258), a proximal opening to allow soft tissue to extend proximally of the device (250). Also, as shown in Figure 7B, the interior of the device (250) may be equipped with soft tissue barbs 264 for additional fixation of the soft tissue included with this device.

Figures 8A and 8B show respectively side and top views of a device (266) much as is shown in Figures 7A and 7B but without an interior cavity for grasping a soft tissue. Instead, in this instance, the soft tissue passes down one exterior cavity (268), preferably having included soft tissue barbs (270) for grasping the soft tissue. The graft then passes through a diametric passageway (273) into the opposite exterior cavity (275) where it preferably is held in place by more tissue barbs. This variation of the inventive anchor (266) clearly places a substantial length of soft tissue graft against the wall of the bone

hole. Additionally, the device (266) has a V-shaped slot (277) providing a bit of "splay" at the proximal end. As was the case with the device shown in Figures 7A and 7B, the device includes lower spring arms (272) which preferably are situated below the cortical plate when the device is installed.

Figures 9A and 9B show still another variation of the invention (290) including screw threads (292) which, in conjunction with upper slot (294) may be used to twist the device (290) into a hole (threaded or not) in a bone.

This device (290) includes one or more longitudinal exterior cavities for grasping the soft tissue. The proximal end of device (290) includes holes (298) at the end of one or more exterior cavities (296) to allow the soft tissue to proceed from anchor (290) proximally to another site. The distal end (300) is also adapted to enter the chosen bone hole. It may be modified to include a thread cutting portion at that distal end (300).

Figure 10A shows a side view of a device (300), that as shown in Figure 10B and 10C, snaps into a generally cylindrical shape after introduction into the bone hole. The installed form is generally a cylinder but contains one or more external cavities for passage of the soft tissue. The external protuberances (304) and soft tissue barbs (306) are shown in this variation. Again, the device is carefully sized in relation to the chosen diameter of the hole, so that there is a tight fit when it progresses from the unsnapped shape as shown in Figure 10B to the snapped shape as shown fully installed in Figure 10C.

Figures 11A and 11B show a variation of the device shown in Figures 10A, 10B, and 10C. In this instance, the radial protuberances (310) on the device (312) are of a different form in that they are teeth or blocks rather than being ridges as shown in Figure 10C. Furthermore, the interior (314) of the device includes soft tissue barbs (316) to allow further grasping attachment of the soft tissue device. Again, the device shown in Figure 11B is inserted loosely into the bone hole and snapped into shape as shown in Figure 10C after the device and its attendant soft tissue are properly positioned.

OTHER SOFT TISSUE-TO-BONE ANCHORS

In this section are described a number of interosseous soft tissue-to-bone anchors in which the anchors themselves may or may not have external cavities for pressing the soft tissue against the bone hole provided for their introduction.

Figure 12A shows one such variation (320). In this variation, the proximal end (322) is smaller than the distal end (324). The soft tissue is preferably simply knotted in the device and installed in the bell-shaped hole in the bone by folding the device (320). As an alternative to folding, the device (320) may be introduced into the chosen hole by slotting it in the manner shown with regard to the device (300), (312) shown in Figures 10A, 10B, 10C, 11A, and 11B.

Figure 13A shows a top view of a device (330) which is inserted into a slot shaped hole in the bone. Figures 13B and 13C, respectively, show side and end views of device (330). This device may have a passageway (332) passing from the interior of device (330) to its exterior. Additionally, the device may have an exterior cavity (334) including soft tissue barbs (336) as desired. Again, optionally, the exterior of the device may have exterior protuberances (340) to assist with fixing the device within the slot in the bone.

Figure 13D shows such bone (342) and placement of the device (330) along with a length of soft tissue (344). The soft tissue (344) extends proximally from the proximal end of exterior cavity (334) and passes distally through the cavity, through passageway (332) and out between the leaves of device (330).

Figure 14A shows a top view and Figure 14A shows a side view of device (350) having passageway (352) extending from the proximal end 354 to the distal end (356). The device (350) is another variation which is fit into a slotted opening in the bone. The interior of the passageway (352) is preferably fitted with soft tissue barbs. The exterior cavity (358) preferably also includes soft tissue barbs (360) as needed. Finally, the exterior surface may also include projections (362) to help lodge the anchor (350) firmly in the slot placed in the bone for receiving this device.

Figure 15A shows another anchor device (380) which is coiled and, unlike the variations shown in Figures 10A, 10B, 10C, 11A, and 11B, is configured in such a way that prior to introduction into the formed hole in the bone, the anchor is larger than that hole. The concept of operation here is that the generally spirally wound device (380) grasps the soft tissue (382) on its interior and when the device is squeezed about the soft tissue (382) firmly holds it using the ridges (384) found both on the inside and the outside of the device (380) and the hole itself (386) in Figure 3B maintains the collapsed condition of the device (380). Device (380) is foraminous and it has a number of holes (392) found in the wall of the device, which holes (392) pass from the interior of the device to its exterior. These holes allow ingrowth between the soft tissue and the bone in hole (386). The device (380) itself is preferably made of a material which is bioerodable and is spring-like so to have a spring fit inside hole (386). The variation shown in Figure (380) has a slight conical taper. That is to say that the distal end of the device (394) has a nominally smaller diameter than the proximal end of the device (396). This aids in the placement of the device in the bone hole (386) shown in Figure 15B. Figure 15B shows the introduction of the device into the hole (386) but it should be noted that the device (380) with its included soft tissue (382) has a significant more distance to travel before it should be released.

Figure 16 shows a top view of a variation (400) of the device surrounding a soft tissue graft (402). In this instance, the device (400) has external protuberances (404) and internal soft tissue barbs (406). Otherwise, the construction and use are the same as for the device shown in Figures 15A and 15B.

Figure 17 shows a perspective view of an anchor device (408) made according to the invention which is not foraminous. It has external protuberances (410) for meshing with the bone in the bone hole but otherwise is quite similar to the variation discussed just above.

Figure 18 shows a variation (412) which is minimal in material content and is designed to rote away in a fashion much more quickly than others and allow the soft tissue to merge and grow into the bone in a quite quick fashion. In this foraminous variation, the holes (414) through the spirally wound sheet (460) are large and square and the external barbs (418) are placed at the junctions of the remaining portions.

Figures 19A and 19B show a device (420) in which soft tissue is grasped by a pair of spring members (422) situated on the interior device (420). The device itself hinges about the distal end (424) of these spring members and when the device is inserted into bone (426) as is shown in Figure 19C, the spring members (424) press against the soft tissue and in turn extend the radial protuberances (428) into the bone (426).

Figures 20A and 20B show another variation (430) of a device which soft tissue (432) is introduced into the center of the device and as the device is introduced into bone hole (434), the soft tissue barbs (436) on the interior of the device (430) grasp the soft tissue (432). The self-camming action about hinge region (438) both extends the rotatable protuberances (440) or bone barbs (440) and the spring region (442) outwardly on a radius so that together they hold a device in place. Figure 20C shows device (430) in place in bone (444). As with some of the other devices noted above, it is desirable to size the proximal portion (446) proximal of barbs (440) so that the proximal length (446) approximates or is greater than the depth of cortical plate (448). In this way, one of the protuberances are extended out into softer bone.

Figures 21A through 21C show a final variation of the inventive bone anchor. In this variation, as was the case with the variation shown in Figures 20A, 20B, and 20C, the device (450) includes a proximal portion (452) having internal soft tissue barbs which grasp the soft tissue (456). The distal portion (458) is generally cylindrical and fits within the hole chosen for the device (450). Desirably, as shown in cross-section in Figure 21C, has interior soft tissue barbs as well.

Preferably, the device is held in place within the bore (460) in the bone by the rotatable protuberances (462) shown in the figures. Again, as the device is pressed into bore (460) in the bone, the two sections of the proximal portion (452) rotate about a common center with respect to each other and the external protuberances (462) are pressed into the bone.

In each of the devices described above, the soft tissue to be introduced into the bone is first inserted into the inventive anchor. The inventive anchor and the tissue are then introduced into the bore or slot shaped hole provided for the specific anchor. Adjustment of the length of the soft tissue graft may, in some instances, be necessary before completion of the introduction of the anchor. This, of course, depends on several factors known to orthopedic surgeons who would use these devices.

In the foregoing description, certain terms have been used for understanding, brevity, and clarity. No unnecessary limitations are to be implied from the use of such terminology, however. This is simply because these words are used for description purposes and are intended to be used broadly and construed in the same way. Moreover, the variations of the device and method illustrated here are only by way of example and that the scope of the invention is not limited to the exact details of construction.

Having now described the invention, the construction, the operation and use of preferred embodiments thereof, it should be appreciated that reasonable mechanical equivalents would be apparent to those skilled in this art. Those variations are considered to be within the equivalence of the claims appended to the specification.

We claim as our invention:

1. An intra-osseous soft tissue-to-bone anchor for contacting said soft tissue to said bone, comprising a longitudinal fixture having a distal and a proximal end and an exterior surface,

said proximal end having an opening for passage of said soft tissue,

said distal end for entering an opening in said bone,

said exterior surface a.) having at least one cavity containing anchor barbs to graspingly accept said soft tissue and at least one cavity being oriented and sized to contact said soft tissue with said opening in said bone and b.) adapted for anchoring said anchor in said opening in a bone.

2. The anchor of claim 1 comprising at least one longitudinal exterior cavity.

3. The anchor of claim 1 comprising multiple longitudinal cavities.

4. The anchor of claim 3 comprising a diametric passageway for passage of soft tissue.

5. The anchor of claim 4 wherein said diametric passageway passes between multiple exterior cavities.

6. The anchor of claim 1 wherein said distal end for entering an opening in said bone in chamfered.

7. The anchor of claim 1 wherein said distal end for entering an opening in said bone further includes a distal end opening.

8. The anchor of claim 1 wherein said exterior surface is adapted for anchoring said anchor in said opening in a bone comprises protuberances on said exterior surface.

9. The anchor of claim 8 wherein said protuberances comprise one or more circumferential ridges.

10. The anchor of claim 9 wherein said protuberances comprise knobs.

11. The anchor of claim 9 wherein said protuberances are movable.

12. The anchor of claim 11 wherein said movable protuberances rotate into said exterior surface.

13. The anchor of claim 1 wherein said exterior surface is generally cylindrical.

14. The anchor of claim 1 wherein said exterior surface is threaded.

15. The anchor of claim 1 wherein said exterior surface is longitudinally cut so-to-form a first form which is generally spiral and which may be snapped to form a generally cylindrical shape in a second form.

16. The anchor of claim 15 having an interior surface which further comprises soft tissue barbs.

17. The anchor of claim 1 wherein said longitudinal fixture is notched to provide a splay at said proximal end.

18. The anchor of claim 1 wherein said longitudinal fixture is in two parts comprising a saddle part comprising said exterior surface and an inner surface and further a rail part fitting within said saddle part comprising said at least one outer cavities.

19. The anchor of claim 1 comprising a folded "V" having a distal fold, an exterior wall, and an opening through said exterior wall near said fold.

20. The anchor of claim 19 further comprising exterior protuberances.

21. The anchor of claim 1 comprising a generally rectangular sheet having at least one passageway between said proximal end and said distal end for passage of tissue between said proximal end and said distal end.

22. The anchor of claim 21 further comprising protuberances on said external surface.

23. The anchor of claim 21 further comprising soft tissue barbs in said passageway.

24. The anchor of claim 1 further comprising extendable spring wings.

25. The anchor of claim 1 wherein said longitudinal fixture comprises multiple longitudinal spring arms splayed at said proximal end.

26. The anchor of claim 1 wherein said longitudinal fixture is comprised of at least on biodegradable material selected from polymers and copolymers.

27. The anchor of claim 26 wherein said polymer or copolymer comprises one or more material selected from the group consisting of polyglycolide, polylactide, poly-α-caprolactone, polydiaxanone, polyglyconate, polylactide-co-glycolide, their mixtures, alloys, and random and block copolymers.

28. The anchor of claim 1 further comprising said soft tissue.

29. The anchor of claim 1 wherein said soft tissue further comprises an osteogenic growth factor.

30. A spiral intra-osseous soft tissue-to-bone anchor comprising:

a spirally wound sheet having a longitudinal axis, an interior surface for graspingly accepting a soft tissue selected from the group consisting of tendon and ligament along said axis as said spirally wound sheet is collapsed around said soft tissue, and an exterior surface for anchoring said anchor in an opening in a bone.

31. The anchor of claim 30 wherein said spirally wound sheet is foraminous.

32. The anchor of claim 30 wherein said spirally wound sheet is not foraminous.

33. The anchor of claim 30 wherein said interior surface is grooved to graspingly accept said soft tissue.

34. The anchor of claim 30 wherein said interior surface contains anchor barbs to graspingly accept said soft tissue.

35. The anchor of claim 30 wherein said exterior surface is grooved to anchor said spiral soft tissue to bone anchor in said bone.

36. The anchor of claim 30 wherein said exterior surface grooves follow said spiral in said spirally wound foraminous sheet.

37. The anchor of claim 30 wherein said exterior surface comprises radial protruberances to anchor said spiral soft tissue to bone anchor in said bone.

38. The anchor of claim 30 wherein said spirally wound sheet comprises at least one biodegradable material selected from polymers and copolymers.

39. The anchor of claim 38 wherein said spirally wound sheet polymer or copolymer comprises one or more materials selected from the group consisting of polyglycolide, polylactide, poly-α-caprolactone, polydiaxanone, polyglyconate, polylactide-co-glycolide, their mixtures, alloys, and random and block copolymers.

40. The anchor of claim 30 further comprising said soft tissue.

41. The anchor of claim 30 wherein said soft tissue further comprises an osteogenic growth factor.

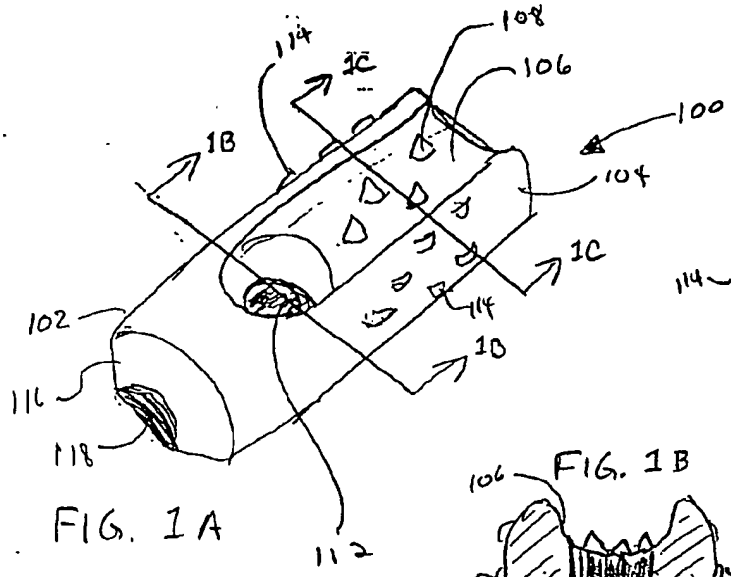


FIG. 1A

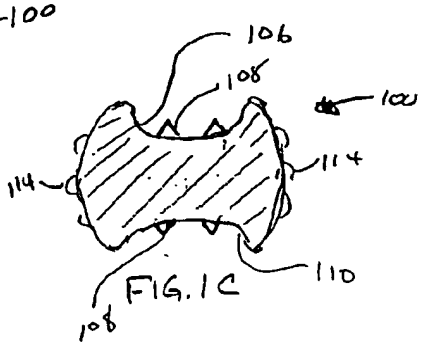


FIG. 1C

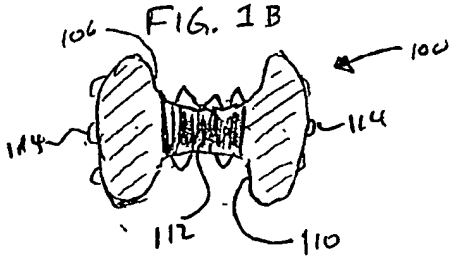


FIG. 1B

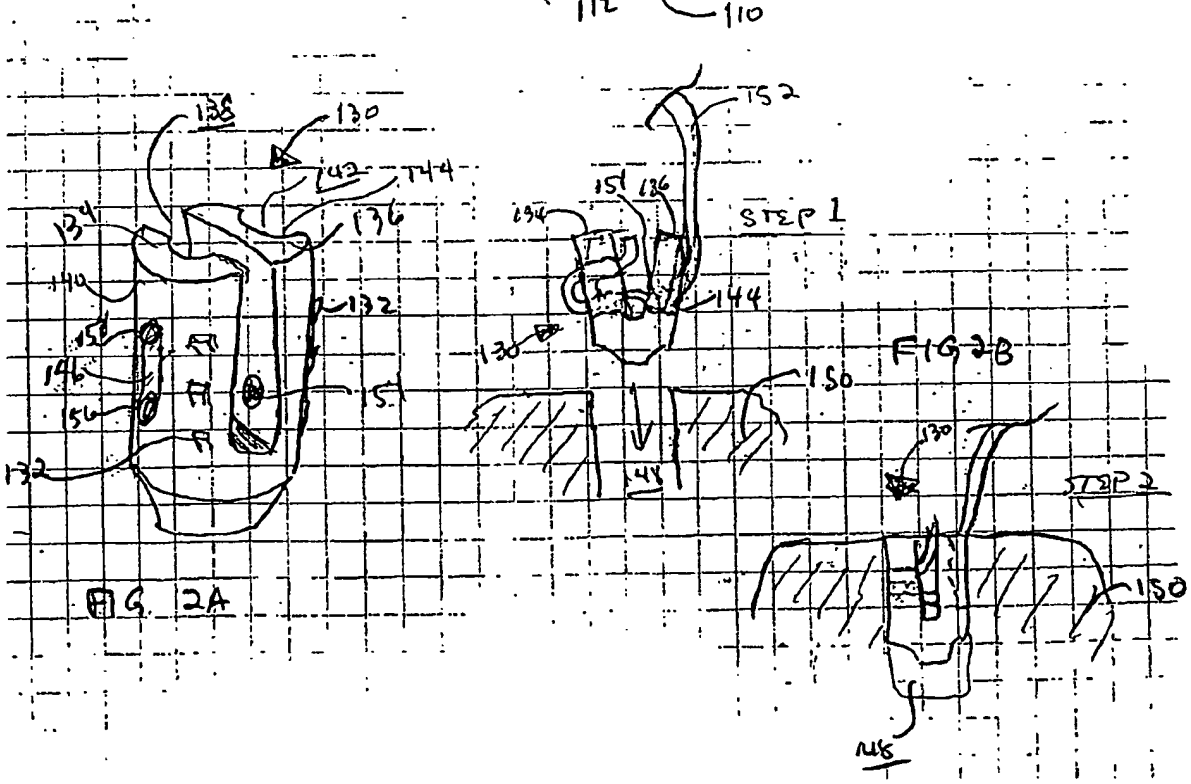


FIG. 2A

FIG. 2B

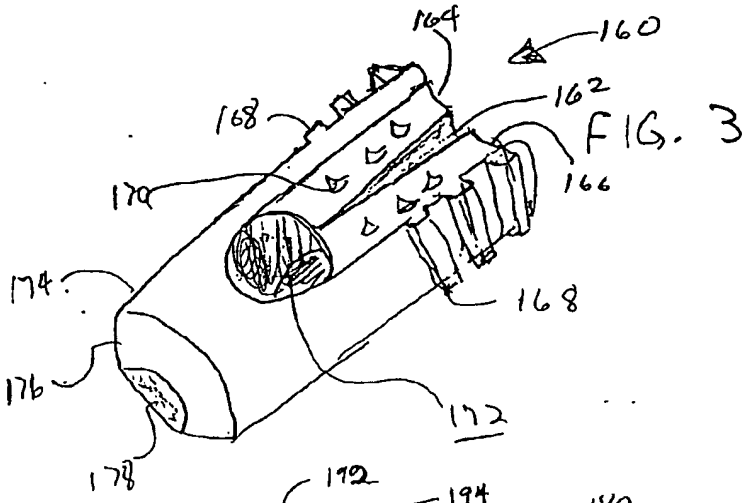


FIG. 3

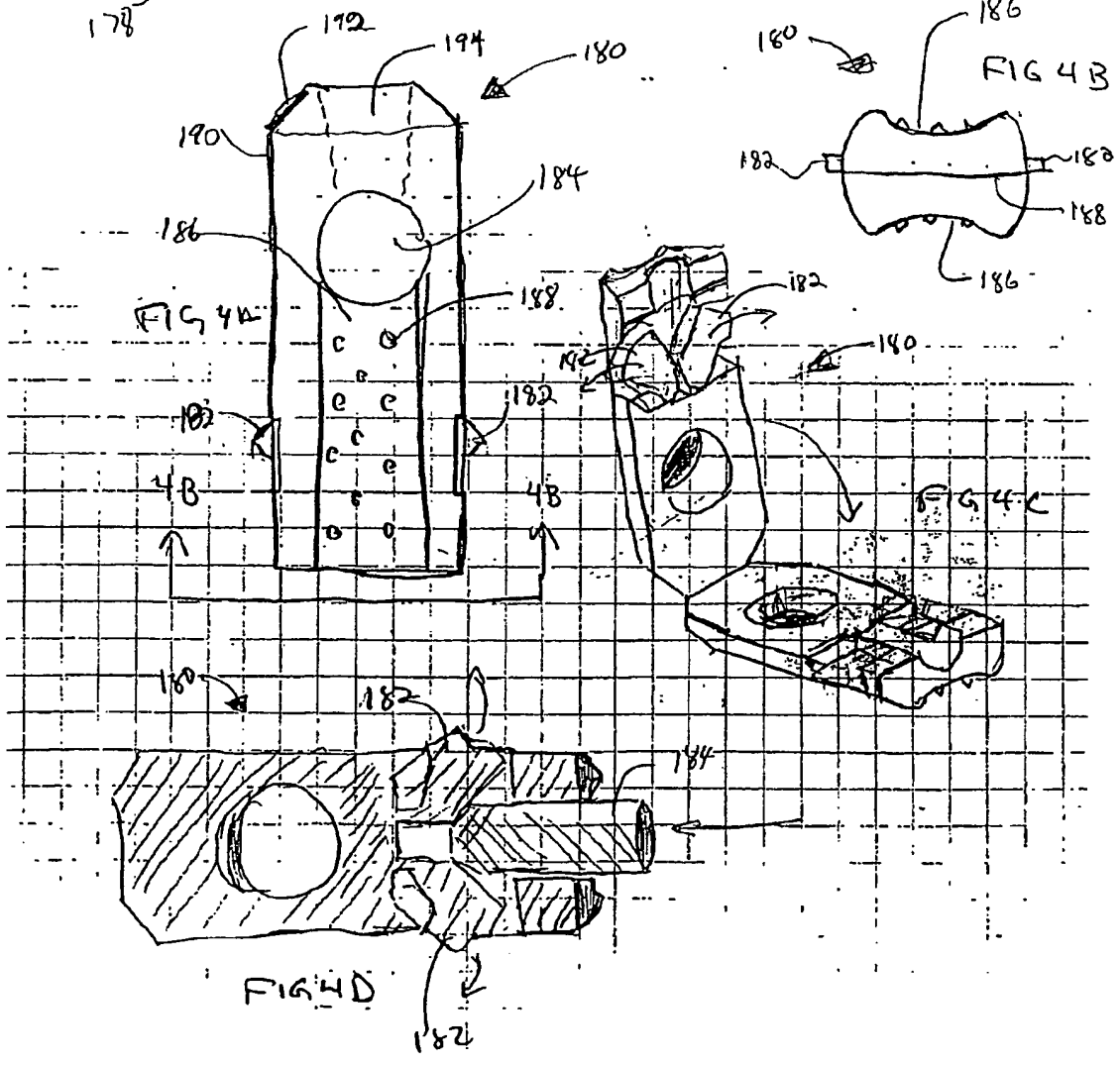


FIG 4A

FIG 4B

FIG 4C

FIG 4D

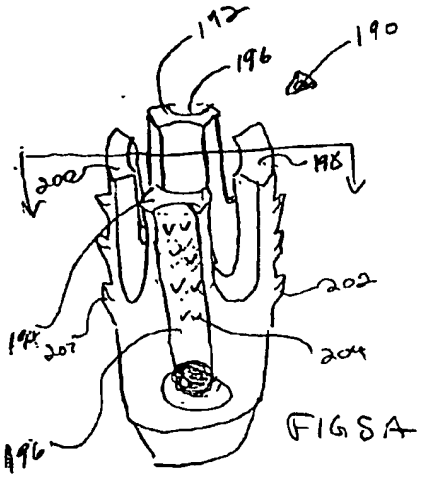


FIG 5A

FIG 5B

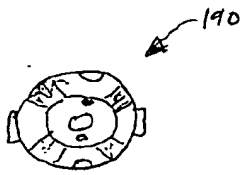


FIG 5C

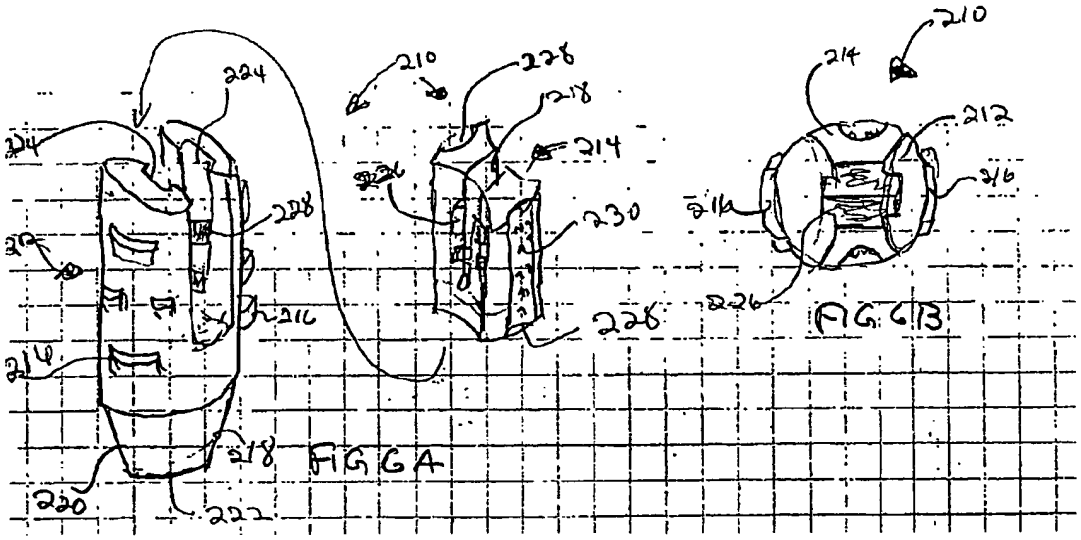


FIG 6A

FIG 6B

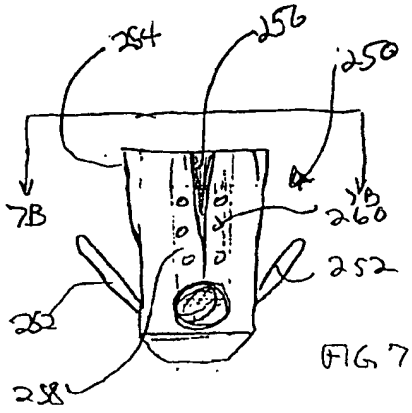


FIG 7A

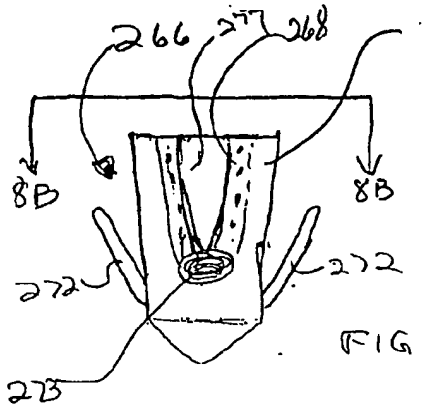


FIG 8A

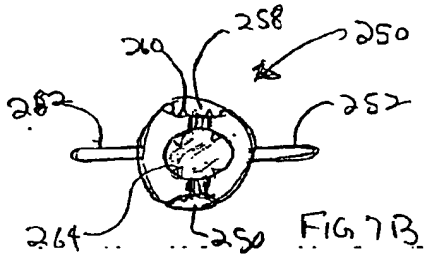


FIG 7B

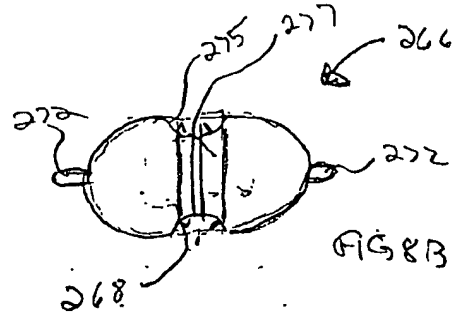


FIG 8B

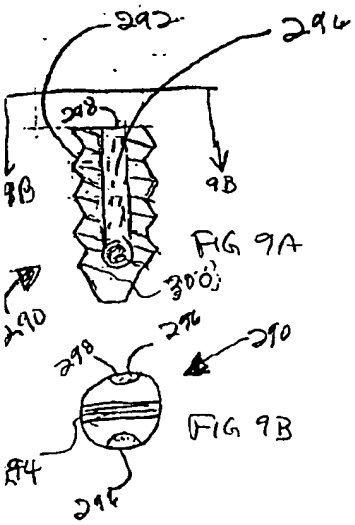


FIG 9A

FIG 9B

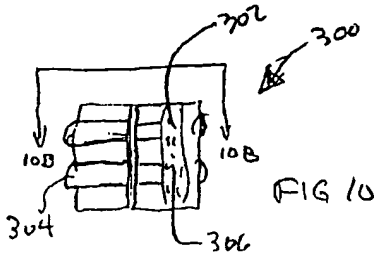


FIG 10A

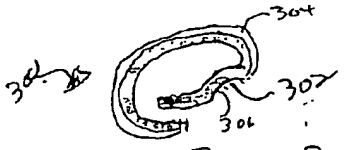


FIG 10B

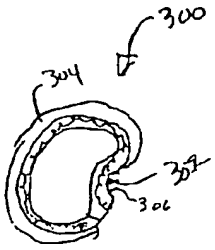


FIG 10C

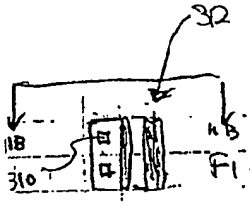


FIG 11A

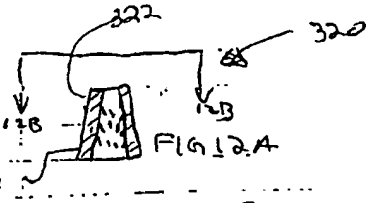
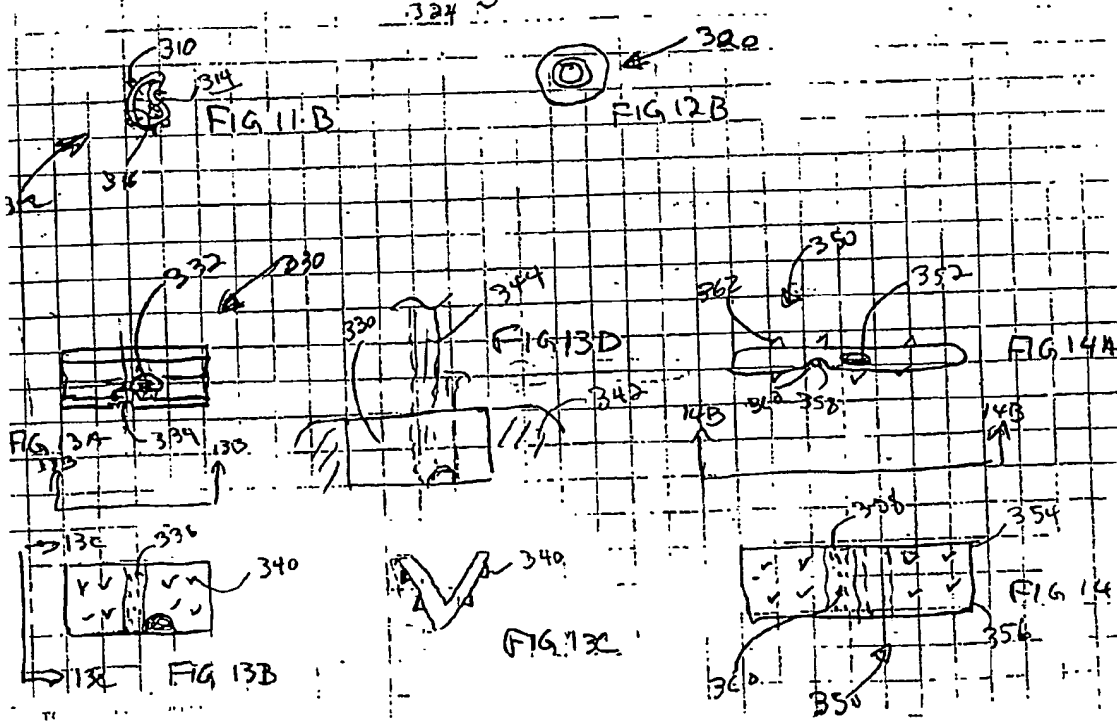


FIG 12A



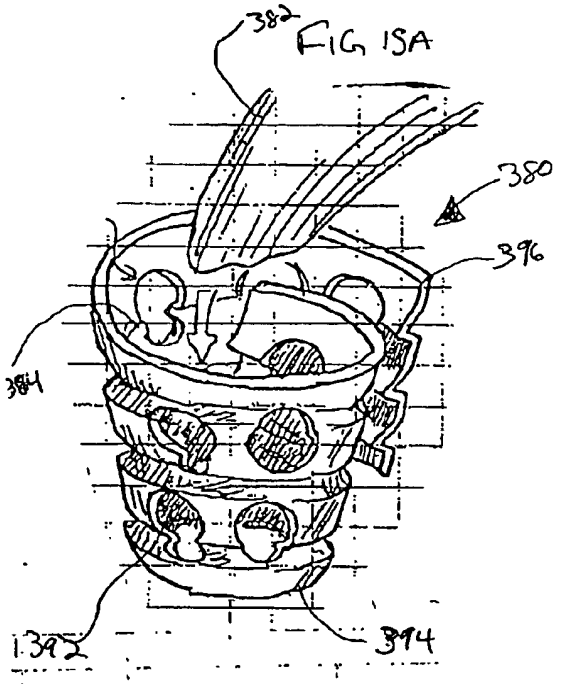


FIG 15A

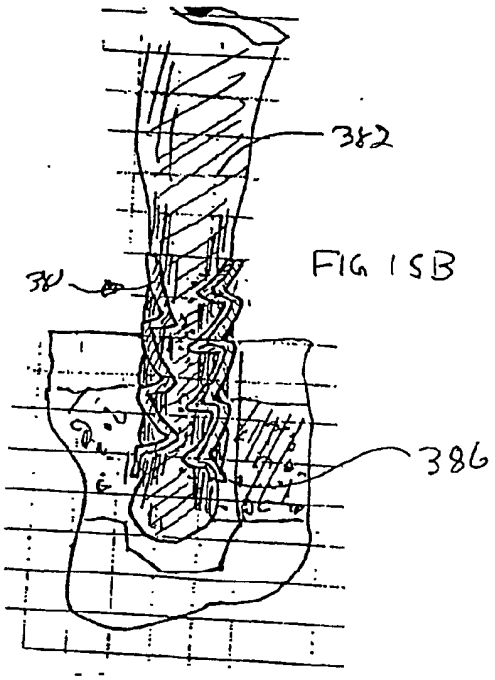


FIG 15B

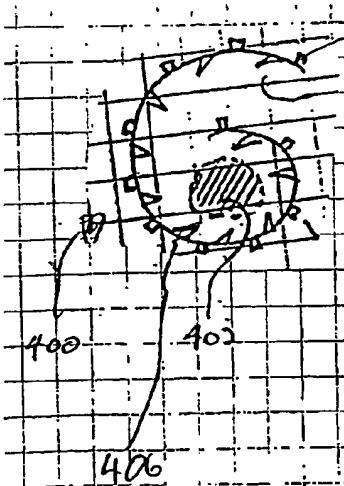


FIG 16

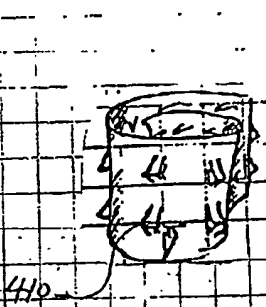


FIG 17

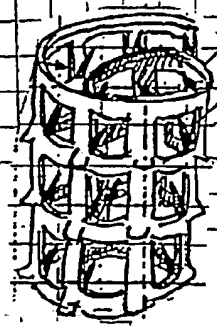


FIG 18

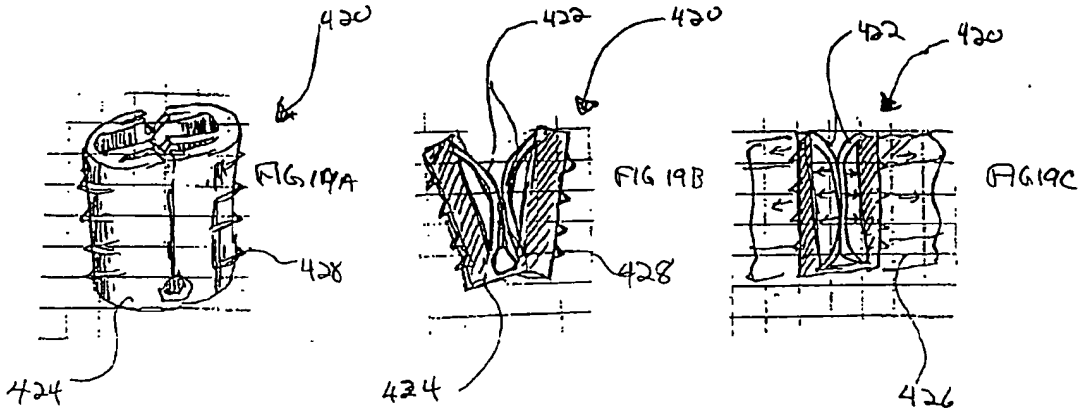

420
FIG 19A
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FIG 19B
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FIG 19C
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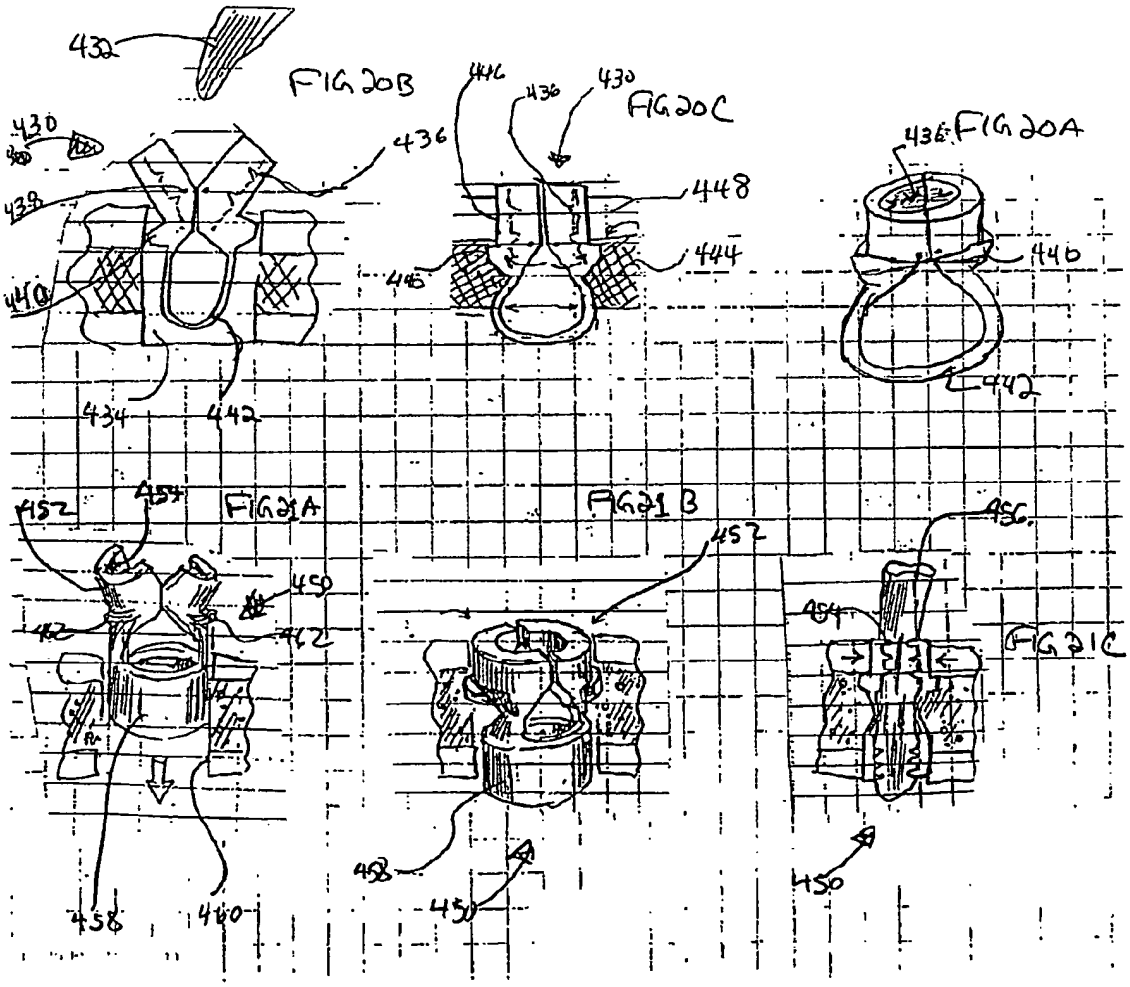
432
FIG 20B
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FIG 20C
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FIG 20A
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FIG 21A
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FIG 21B
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FIG 21C
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